Innovations Expand Types of Seasonal Influenza Vaccines

Many of the projected 135-139 million doses of influenza vaccines being produced for this flu season for use in the U.S. are now available to consumers from six manufacturers licensed by the Food and Drug Administration (FDA).

A variety of flu vaccines, including some that were not available during past influenza seasons, are available this year. This includes a vaccine that protects against four strains of the virus—two strains of type A and two of type B—rather than the traditional protection against three strains--two of type A and one of type B.

In addition, a vaccine that is produced by growing the virus in cells rather than in eggs will be available for use in people 18 years of age and older.

Unlike eggs, cells can be frozen for later use to grow large volumes of cells for the production of vaccine. This could provide a faster start-up time of the manufacturing process for any unexpected need.

"New technologies are providing additional and diverse influenza vaccines, which helps to ensure an adequate supply in the Unites States," said Karen Midthun, M.D., director of FDA's Center for Biologics Evaluation and Research.

"Influenza seasons are unpredictable and can be severe, even deadly," she added. "Last year's influenza season brought an increase in reported hospitalizations and deaths compared to recent years, and vaccination is the best defense to prevent influenza."

All of the vaccines have been determined by FDA to be safe and effective. Getting vaccinated early, before flu season is in full swing, is key to prevention.

An Exacting Process

Manufacturing flu vaccines is an exacting and complex process. New vaccines must be produced each year because the viruses change from year to year and because the protection received the previous year diminishes over time.

Each February, before one flu season

FDA's website has specific information about each flu vaccine, including the FDA-approved age range of use.

www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094045.htm

The website also provides the names of the influenza viruses included in this season's vaccines and an up-to-date list of the number of vaccine lots that have been released for each manufacturer.

www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm343828.htm

ends, the FDA, World Health Organization, the Centers for Disease Control and Prevention (CDC) and other public health experts collaborate on collecting and reviewing data to identify the virus strains likely to cause the most illnesses in the next flu season. Based on that information and the recommendations of an FDA advisory committee, FDA selects the strains for manufacturers to include in their vaccines for use in the United States.

Both egg-based flu vaccines and vaccines made with newer technologies work the same way; they trigger the immune system of the person receiving the vaccine to produce antibodies capable of attacking the virus.

Vaccines are available in a variety of delivery methods, as a needle into muscle, as a needle injected into skin (approved for ages 18 through 64), and as a nasal spray (approved for people ages 2 through 49). In addition, one vaccine made in a high dose formulation is approved for people 65 years of age and older.

The Procedure

Under traditional egg-based production methods, once the influenza viruses have been selected, they are adapted for use in manufacturing and provided to companies licensed by FDA. The manufacturers inject each virus strain into eggs, which are incubated for several days to allow the virus to multiply.

The virus-loaded fluid from the eggs is then harvested and purified.

Manufacturers grow each strain separately then test it, including for potency. Then the strains are mixed and tested again. Once divided into standard dosages, the vaccines are put into containers such as vials, syringes or sprayers.

Test results are submitted to FDA, along with samples from each batch, or lot. FDA reviews the test results and the samples before releasing the vaccine for distribution in the United States. Each lot, or batch, undergoes testing before release by FDA.

FDA also inspects the manufacturing facilities on a regular basis and continues to monitor the safety of the vaccines once they are in use by the public.

The level of effectiveness can depend on the health and immune system of individuals and how well a particular season's vaccine strains match circulating flu strains.

There is a possibility of a less than optimal match between the virus strains predicted to circulate and the virus strains that end up causing the most illness. However, even if the vaccine and the circulating strains are not an exact match, the vaccine may reduce the severity of the illness and help prevent influenza-related complications.

CDC recommends that everyone six months of age and older get vaccinated soon after vaccine becomes available. Those people for whom vaccination is particularly important include young children, the elderly, pregnant women, and those who suffer from a variety of chronic illnesses, including asthma, diabetes and heart disease.

Although the winter months are usually the peak month for flu activity, influenza disease in people typically begins appearing in October.

FDA's website has specific information about each flu vaccine, including the FDA-approved age range of use. The website also provides the names of the influenza viruses included in this season's vaccines and an up-to-date list of the number of vaccine lots that have been released for each manufacturer. FDA

Find this and other Consumer Updates at *www.fda.gov/ForConsumers/ConsumerUpdates*

Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*